

U.S. Patent Application Serial No. 10/087,449

### **REMARKS**

The following remarks address rejections and comments made in the Office Action mailed January 6, 2009. Claims 1, 12, and 19 are currently amended, and no claims are currently cancelled. Claims 1-25 are currently pending.

In light of the foregoing amendments and the following remarks, the applicant respectfully requests reconsideration of the present case in view of the following remarks.

#### **1. Claim Objections**

The Office Action objected to claim 1 for alleged grammatical errors, but did not explain the error. The applicant respectfully traverses this objection, but has amended the claim to delete the hyphen between the terms "user" and "interface." This amendment is clarifying only and does not change the scope of the claim.

The Office Action also objected to claim 12 alleging the term "a user" is grammatically incorrect, but did not explain how the term is grammatically incorrect. The applicant respectfully traverses this objection and notes the office action did not explain the grammatical error. The applicant has amended claim 12 to change the term "user" in line 2 to the term "person." This amendment is clarifying only and does not change the scope of the claim. Because of this amendment, the applicant respectfully submits the objection is moot and requests withdrawal of the rejection.

Although there was not a specific objection or rejection to claim 19, the term "uniquely" did not have antecedent basis and it was amended to read "user-defined." This amendment is clarifying only and does not narrow the scope of the claim.

#### **2. Rejection of claims 12-25 under 35 U.S.C. § 102**

Claims 12-25 stand rejected as being anticipated by the Estes (U.S. Publication No. 2003/0114836). The applicant respectfully traverses this rejection and does not concede any characterizations of the pending application or cited references set forth in the Office Action.

Claims 12-18 recite, "storing . . . a set of operating parameters . . . at least one of the operating parameters being a user-defined identifying name." Claims 19-25 recite, "a processor . . . programmed to assign the set of operating parameters to the delivery program upon selection of the user-defined identifying name." The term "user-defined" must be interpreted consistent

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with the specification. See M.P.E.P. § 2111. In this case, the specification teaches a user-defined field is not limited to a particular type of information such as a patient name. Rather it is customizable with whatever characters a user chooses to use. As a non-limiting example, the pending specification discusses user entry of a custom name for a delivery program. Page 76, lines 14-22. Such user-defined identifying names allow a user to assign names that are meaningful to them.

In support of this rejection, the Office Action equates "uniquely identifying name" with "user-defined identifying name." It also cites ¶ 63 and Figure 5 from Estes. However, this passage from Estes discusses only a table illustrated in Figure 5 that displays a historical record of alarms and events. Estes, ¶ 63:4-6. Additionally, a previous Office Action mailed on March 13, 2008, states that the patient name illustrated in Figure 5 of Estes was a user-defined identifying name. However, the field in which the patient name is entered is not user-defined as that term is used in the pending claims. The name field in Estes must include the name a patient; the data is defined by the patient's name, not by the user. The user cannot define or customize the data that is entered into the field.

For at least these reasons, the applicant respectfully submits that claims 12-25 are not anticipated by Estes and request withdrawal of the pending rejection.

**3. Rejection of claims 12-25 under 35 U.S.C. § 102 or § 103**

Claims 12-25 stand rejected under 35 U.S.C. § 102(e) as being anticipated by the Estes (U.S. Publication No. 2003/0114836), or in the alternative, under 35 U.S.C. § 103(a) as being obvious over Estes in view of Levine (U.S. Publication No. 2003/0011646). The applicant respectfully traverses this rejection and does not concede any characterizations of the pending application or cited references set forth in the Final Office Action.

Claims 12-18 recite, "selecting the user-defined identifying name thereby assigning the set of operating parameters identified by the user-defined identifying name to the delivery program; and running the delivery program, the delivery program executing the set of operating parameters thereby controlling the infusion pump to deliver the therapeutic agent according to the delivery schedule defined by the set of operating parameters." Claims 19-25 similarly recite, "a processor . . . programmed to assign the set of operating parameters to the delivery program upon selection of the user-defined identifying name and to execute the set of operating

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parameters thereby controlling the pump mechanism to deliver the therapeutic agent according to the delivery schedule.”

As discussed above, Estes fails to teach or suggest a user-defined identifying name as recited in the claims. In Estes, any field that includes the name of a patient or the name of a function (e.g., BOLUS DELIVERY, ¶ 73 and Figure 6) is not user-defined. The field cannot include customizable data; it must include the actual name of the patient or the actual name of the function.

Levine also fails to teach or suggest a “user-defined identifying name.” The passages from Levine cited in the office action teach that information about medication prescribed by a different healthcare practitioner is entered to track a patient’s healthcare history to prevent possible adverse drug interactions. Levine, ¶¶ 147:1-7 and 148:1-4. The information about these historical medications includes the name of the medication, when it was taken, its dosage, and the purpose of the medication. This information does not include user-defined names, but rather the names of medications.

Additionally, any combination of Estes and Levine would result in a pump that does not properly deliver fluid. The cited teachings of Levine disclose historical information for medication that is different than the pump operating parameters prescribed by the healthcare practitioner. Selecting this historical data to control delivery of the therapeutic agent as recited in the claims potentially would result in the wrong delivery rates, which could be dangerous or even fatal to the patient. The combination of elements proposed in the office action would not work.

Therefore, the combination of the cited references would not result in a combination that includes a “user-defined identifying name” as recited in the claims. Even if these references were combined, the resulting combination of elements would be inoperable. Therefore, the applicant respectfully submits that claims 12-25 are not obvious for at least the reasons stated above, and requests withdrawal of the pending rejection.

**4. Rejection of claims 1-11, 13-18, and 20-25 under 35 U.S.C. § 103**

Claims 1-11, 13-18, and 20-25 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Estes in view of Levine. The applicant traverses this rejection and does not concede any

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characterizations of the pending application or cited references set forth in the Final Office Action.

**a. Claims 1-7 and 9-11**

Claims 1-7 recite, "a table . . . containing a row, the row having a plurality of cells, each cell in the row relating to a different operating parameter for the delivery program; entering an operating parameter into at least one of the cells in the table . . . and downloading the operating parameters into the pump." Claims 9-11 recite, "a processor . . . programmed to (a) generate a table on a user interface, the table containing a row, the row having a plurality of cells, each cell in the row relating to a different operating parameter for the delivery program; (b) receive data directly from the data entry device and display the data in one or more of the cells; and (c) download the operating parameters displayed in the cells to the infusion pump."

Paragraph 21 of the office action acknowledges that Estes fails to teach or suggest entering or receiving an operating parameter into at least one of the cells in the table. Levine also fails to teach or suggest entering an operating parameter into at least one of the cells. The office action cites Figure 23 (elements 1800, 1812) and paragraph 147 from Levine as teaching entering an operating parameter into at least one of the cells. However, element 1812 is an entry box "in which the patient enters information about other medications." Levine, ¶ 147:12-13 (emphasis added). The patient enters historical information, not operating parameters that will be downloaded into the pump. As explained above, the disclosure from Levine that is cited in the office action teaches entering historical information that a healthcare practitioner (not the pump) uses to prevent adverse drug interactions. See Levine, ¶¶ 147 and 148.

Therefore, no combination of Estes and Levine can result in the claimed combination of elements recited in claims 1-7. Additionally, one would not think to combine the cited teachings from Levine with Estes, because the result would be downloading incorrect data to the pump. The applicant respectfully submits that claims 1-7 are not obvious over Estes in view of Levine for at least the reasons stated above and requests withdrawal of the pending rejection.

**b. Claim 8**

Claim 8 recites, "each data set in the plurality of data sets contains the same type of operating parameters and at least two of the data sets contain different values for the same type of operating parameter; storing the plurality of data sets in memory [of the pump]; selecting one

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of the plurality of data sets; and running a delivery program wherein the delivery program executes the operating parameters.”

Paragraph 28 of the Office Action acknowledges that <sup>63</sup>Estes fails to teach or suggest that each data set in the plurality of data sets contains the same type of operating parameters and at least two of the data sets contain different values for the same type of operating parameter. Levine also fails to teach this element. As explained above, the disclosure from Levine cited in support of the rejection does not teach or suggest operating parameters. The disclosure teaches entry of historical information related to other medications for use by healthcare practitioners to prevent adverse drug interactions. Additionally, a pump that would use this historical information to execute a delivery program would not properly deliver the medication.

Therefore no combination of the cited references can result in the claimed combination of elements recited in claim 8. Additionally, one would not think to combine the cited teachings from Levine with Estes, because the result would be downloading incorrect data to the pump. The applicant respectfully submits that claim 8 is not obvious over Estes in view of Levine for at least the reasons stated above and requests withdrawal of the pending rejection.

*c. Claims 13-18*

Claims 13-18 depend from and include all of the elements recited in claim 12, which is patentably distinct from Estes and Levine for at least the reasons stated above. Therefore, the applicant respectfully submits claims 13-18 are not obvious over the cited references and requests withdrawal of the pending rejection.

*d. Claims 20-25*

Claims 20-25 depend from and include all of the elements recited in claim 19, which is patentably distinct from Estes and Levine for at least the reasons stated above. Therefore, the applicant respectfully submits claims 20-25 are not obvious over the cited references and requests withdrawal of the pending rejection.

**CONCLUSION**

In view of the above amendments and remarks, the applicant respectfully requests withdrawal of the pending rejections and issuance of a Notice of Allowance. The applicant notes that there may be reasons that the pending claims are patentably distinct from the cited reference in addition to those set forth herein and reserves the right to raise argument in support of

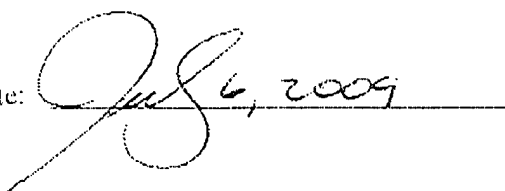
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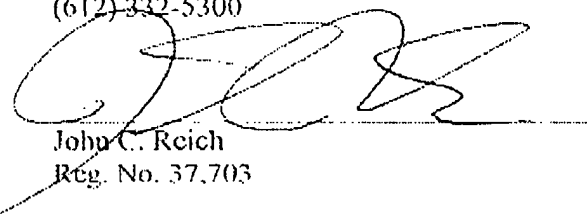
patentability in the future. If the examiner believes a telephone conference would advance the prosecution of this application, the examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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Date:

 July 6, 2009

  
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